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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,734	09/29/2000	Charles Joel Amtzen	P00245US D	1914

7590

05/29/2002

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/29/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/676,734

Applicant(s)

ARNTZEN ET AL.

Examiner

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-75, 83-85, 88, 91 and 98-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-75 and 83-85, 88, 91 and 98-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Claim Objections

Claim 88 is objected to because of the following informalities: the claim omits commas between "claim 73" and "said plant", and between "the animal" and "elicits".

Appropriate correction is required.

Claim 91 is objected to because of the following informalities: the claim omits commas between "tissue" and "wherein". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 83-85 and 98 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a transgenic plant expressing a recombinant animal viral antigen protein, at a level of about .03% or more of total soluble protein, at a level of about .05% or more of total soluble protein, or at a level of about .1% or more of total soluble protein. The claims are also drawn to transgenic plant tissue in which a recombinant protein is expressed at a level sufficient to elicit an immune response against a viral antigen when said tissue is orally administered to an animal.

First, while one of skill in the art can readily express a recombinant protein in a plant cell, the level at which a recombinant protein is expressed is dependent on a variety of factors, such as the vector used to express the protein, the protein expressed, and the

species of plant transformed. Although Applicant has disclosed how to make transgenic tobacco and tomato plants that express recombinant hepatitis B viral surface antigen protein (pages 29-32), Applicant has not disclosed how to make transgenic plants that express a recombinant animal viral antigen protein at a level of about .03% or more of total soluble protein, at a level of about .05% or more of total soluble protein, or at a level of about .1% or more of total soluble protein. Applicant has not disclosed the type of vector to be used, the type of animal viral protein to be expressed, or the type of plant to be transformed such that a recombinant animal viral protein is expressed at .03%, .05% or .1% or more of total soluble protein. The specification does not provide sufficient guidance for one of skill in the art to make, without undue experimentation, transgenic plants that express a recombinant animal viral antigen protein at the claimed levels.

Second, while one of skill in the art would recognize that an antigen could be used to elicit an immune response by oral administration, the ability of an antigen to elicit an immune response when administered orally is dependent on the dosage of the antigen and the manner in which it is administered. Applicant has not disclosed the level at which a recombinant protein must be expressed in order for transgenic plant tissue to elicit an immune response against a viral antigen when said tissue is orally administered to an animal. Applicant also has not disclosed the manner in which such tissue should be administered to an animal in order to elicit an immune response. The specification does not provide sufficient guidance for one of skill in the art to make and use, without undue experimentation, transgenic plants that express a recombinant animal viral antigen protein at a level sufficient to elicit an immune response when orally administered to an animal.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 98-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 98 is indefinite in the recitation of "A transgenic plant having plant tissue, expressing a recombinant protein". It is unclear whether the plant or the plant tissue is expressing a recombinant protein.

Claims 99-100 are indefinite in the recitation of "said plant". It is unclear whether said plant refers to "a plant comprising a protein", or "a transgenic plant".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 73-75, 88, 91 and 99-100 are rejected under 35 U.S.C. 102(e) as being anticipated by Goodman et al. (US 4,956,282, September 11, 1990).

The claims are drawn to a transgenic plant expressing a recombinant animal viral antigen protein, a transgenic plant expressing a chimeric recombinant animal viral antigen protein fused to another peptide, polypeptide or protein, a transgenic tomato plant expressing a recombinant animal viral antigen protein, plant tissue obtained from a transgenic plant expressing a recombinant animal viral antigen protein, said tissue eliciting an antigenic response when orally administered to an animal, and edible plant tissue obtained from a transgenic plant expressing a recombinant animal viral antigen protein. Additionally, the claims are drawn to a plant comprising a protein which triggers production of antibodies to a viral protein, and to hepatitis or transmissible gastroenteritis virus protein, said protein being produced by expression in a transgenic plant.

Goodman et al. teach transgenic plants expressing recombinant animal viral antigen proteins from leukemia and lymphotropic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (column 3 lines 30-35). Goodman et al. also teach transgenic plants expressing chimeric recombinant animal viral antigen proteins fused to a transit or leader peptide from a plant peptide (column 3 lines 50-53). Additionally, Goodman et al. teach the use of tomato plants to express these proteins, as well as the use of other edible plants (column 4 line 59). Although Goodman et al. do not explicitly teach an antigenic response in animals upon oral administration of tissue obtained from these plants, these plants would inherently possess the ability to elicit an antigenic response, given that a certain subpopulation of animals will always have an antigenic response to the oral administration of plant tissue per se. Furthermore, the viral proteins taught by

Goodman et al. are expressed in a plant, and would inherently trigger the production of antibodies to a viral protein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 73-75, 83-85, 88, 91 and 98-100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,612,487. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of U.S. Patent No. 5,612,487 is drawn to a transgenic tobacco plant capable of expressing a recombinant hepatitis B viral surface antigen protein, whereas claims 73-75, 83-88, 91 and 98-100 of the instant application are drawn to transgenic plants expressing recombinant animal antigen proteins.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
May 22, 2002


PHUONG T. BUI
PRIMARY EXAMINER
5/22/02